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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,281	11/30/2001	Wen-Jen Hwu	9516-026-999	2126

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EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,281	HWU, WEN-JEN	
	Examiner	Art Unit	
	Clinton Ostrup	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/14/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3 and 6-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3 and 6-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2,3 and 6-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10/14/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 2-3 and 6-21 are pending in this application.

Priority

Priority to U.S. Provisional Application Number 60/250,130, filed December 1, 2000, has been acknowledged.

Election/Restrictions

The examiner has expanded the search and examination of the elected species to other forms of metastatic cancer, as no claims currently claim the elected species, metastatic brain cancer.

Response to Applicant's Arguments/Amendment

Applicant's arguments filed October 14, 2003, to the rejection of claims 1-21 under 35 U.S.C. 103have been fully considered and deemed persuasive because applicant correctly noted on page 5 of their response that an article published after the filing date of their application is not prior art. Therefore, the said rejection has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 2-3, 6-10, 12-14, 16-17, and 19-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Arance et al., Three-arm Phase II study of temozolomide (TMZ) in metastatic melanoma (MM): preliminary results.

Arance et al., report the preliminary results of an ongoing three-arm phase II study aiming to assess the efficacy of temozolomide in an 8-hour schedule against the 24-hour schedule in combination with either interferon alpha or thalidomide in metastatic melanoma. The reference teaches arm C of the study as (oral temozolomide at 150 mg/m2 days 1-5 and oral thalidomide at 100mg daily for 28 days) with cycles being repeated every 28 days for up to one year. The reference teaches the median age of patients as being 55 years old, with a range of 17-78 years of age. Therefore, the reference teaches the dosage schedules of instant claims 6, 13, 14, 16-17, the amounts of temozolomide and thalidomide of instant claims 7-10, 12-13, and 19-21, the age range of instant claim 13, and the metastatic cancer of instant claims 2-3. Finally, the reference teaches that when temozolomide was combined with thalidomide and administered to patients with metastatic melanoma, the treatment was active and well tolerated. See: abstract.

Claims 2-3, 6, 15, and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Chemotherapeutic Strategies, American Society of Clinical Oncology 36th Annual Meeting, Day 4, May 23, 2000.

Chemotherapeutic Strategies teaches that Dr. Arance and colleagues from the Christine Hospital in Manchester, England, compared response rates and survival in metastatic melanoma patients receiving either 5 doses spaced 8 hours apart of

temozolomide, temozolomide for 5 days with INF-alpha, or temozolomide for 5 days with thalidomide. Therefore, the primary reference clearly teaches that metastatic melanoma has been treated by administering temozolomide and thalidomide, as claimed instantly in claims 2-3, 6, 15, and 17.

Claim Rejections - 35 USC § 103

Claims 2, 11, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arance et al., Three-arm Phase II study of temozolomide (TMZ) in metastatic melanoma (MM): preliminary results and further in view of Newton Novel Chemotherapeutic Agents for the Treatment of Brain Cancer.

Arance et al., report the preliminary results of an ongoing three-arm phase II study aiming to assess the efficacy of temozolomide in an 8-hour schedule against the 24-hour schedule in combination with either interferon alpha or thalidomide in metastatic melanoma. The reference teaches arm C of the study as (oral temozolomide at 150 mg/m2 days 1-5 and oral thalidomide at 100mg daily for 28 days) with cycles being repeated every 28 days for up to one year. The reference teaches the median age of patients as being 55 years old, with a range of 17-78 years of age. Therefore, the reference teaches the dosage schedules of instant claims 6, 13, 14, 16-17, the amounts of temozolomide and thalidomide of instant claims 7-10, 12-13, and 19-21, the age range of instant claim 13, and the metastatic cancer of instant claims 2-3. Finally, the reference teaches that when temozolomide was combined with thalidomide and administered to patients with metastatic melanoma, the treatment was active and well tolerated. See: abstract.

Although the primary reference teaches the combination of both temozolomide and thalidomide for the treatment of metastatic melanomas, the reference lacks the amounts of temozolomide of instant claim 11, and the dosage schedule of instant claim 18.

While the reference is silent regarding the amount of temozolomide as claimed in claim 11, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation. *In re Aller,* 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

In regard to the dosage schedule of instant claim 18, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the dosage schedule to allow a rest period for the patient after 6 weeks because of the reasonable expectation that the patient would need a rest period to counter act the myelosuppression side effect of administering temozolomide in combination with thalidomide.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Zeldis et al., US 2002/0035090 A1 is being supplied because it teaches compositions comprising thalidomide and at least one other anti-cancer drug for the treatment of cancer and teaches temozolomide as an example of anticancer drugs that can be used in the invention. See: page 8, [0069] – page 9, [0071].

However, this reference was not used in an art rejection because of the long list of drugs cited as anti-cancer drugs that can be used in the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup
Examiner
Art Unit 1614

Frederick Krass
Primary Examiner
Art Unit 1614